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Award Number: DAMD17-02-2-0017

TITLE: Population Health Trail for Smokeless Tobacco Cessation with Military Personnel

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CONTRACTING ORGANIZATION: Oregon Research Institute
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REPORT DATE: May 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	May 2005	Annual (1 May 2004 - 30 Apr 2005)

4. TITLE AND SUBTITLE
Population Health Trail for Smokeless Tobacco Cessation with Military Personnel

5. FUNDING NUMBERS
DAMD17-02-2-0017

6. AUTHOR(S)
Herbert H. Severson, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

While smoking cessation has received considerable attention within the military, the use of smokeless tobacco (chewing tobacco and snuff) has not been a focus of medical services or research. Epidemiological data suggest that while smoking has continued to decline both in the general population and within the military, the use of smokeless tobacco products has increased. The primary objective of this research is to develop and evaluate an intervention for smokeless tobacco cessation comprised of proactive recruitment, targeted written and video materials mailed to the participant, and phone call support. At the end of this third year of the study, several accomplishments have been achieved. Accomplishments include visits for orientation and training at dental clinics at 14 additional military installations: 6 AF sites were added for enrollment purposes; 5 Army sites; Camp Pendleton, CA, for Marine enrollment; and 2 Navy clinics in San Diego for enrollment of Navy personnel. A total of 667 participants have now enrolled in the study. Mailed follow-up assessments at three and six months post enrollment were continued, with 313 three-month surveys and 233 six-month surveys completed to date.

14. SUBJECT TERMS
Smokeless tobacco cessation, military, organizational support, randomized trial, population-based, tobacco cessation

15. NUMBER OF PAGES
37

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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INTRODUCTION

While smoking cessation has received considerable attention within the military, the use of smokeless tobacco (chewing tobacco and snuff) has not been a focus of medical services or research. Epidemiological data suggest that while smoking has continued to decline both in the general population and within the military, the use of smokeless tobacco products has increased. The primary objective of this research is to develop and evaluate an intervention for smokeless tobacco cessation comprised of proactive recruitment, targeted written and video materials mailed to the participant, and phone call support. The primary hypothesis to be tested is that participants randomized to receive the intervention will quit their tobacco use at a significantly higher rate than participants receiving usual care. Active duty U.S. Armed Forces personnel stationed at military locations that are identified as current ST users when completing their annual preventive oral health assessment will be recruited to participate in a randomized two-group design that compares a brief contact intervention with the usual preventive health care. Follow up assessments by mail at 3- and 6-months after randomization will assess the impact of the program.

BODY

In the third year of our grant, we requested and received approval from the IRB at Brooke Army Medical Center (BAMC), TX, to enroll participants at three Army sites in the Great Plains Medical Region: Ft Leavenworth, KS, Ft Polk, LA, and Ft Sill, OK. In addition, we requested and received approval from the Walter Reed Army Medical Center to enroll participants at two additional Army sites in the North Atlantic Medical Region: Ft Drum, NY in Year-02, and Ft Knox, KY, in Year-03. Approval for our protocol was previously granted (May 11, 2004) by the Naval Hospital, which is the IRB of record for the Naval Dental Center Southwest and Camp Pendleton in San Diego. Recruitment has been underway at these Army, Navy, and Marine sites in the third year of our grant. In addition, five additional Air Force sites were approved for participation by the Wilford Hall Medical Center (WHMC) IRB: Robins AFB, GA, Mt Home AFB, ID, Little Rock AFB, AR, Langley AFB, VA, and Nellis AFB, NV. A sixth AFB, Eglin AFB, FL, was approved for participation by the Eglin Medical Center IRB. In total our study is involved with recruiting participants at 21 military bases as listed in the table below.

To optimize enrollment of volunteers into the trial, we visited each new site and conducted orientation and training with the dental clinic providers and staff. It is the providers who are the ones who first approach potential participants with the opportunity to enroll in the study. Across all sites where we are presently recruiting, we have enrolled 667 participants to date. For the 334 participants assigned to the Treatment Group, we have completed approximately 761 telephone counseling calls. We are also in the process of collecting three and six-month follow-up assessments via mail. We use telephone surveys for participants not responding to mailed surveys. To date we have collected 313 three-month follow-up assessments and 233 six-month assessments. We have collected three-month follow-up data from approximately 66% of participants who have reached the three-month follow-up assessment and approximately 67% from participants who have reached the six-month follow-up assessment.

Recruitment of Intervention Sites

Listed below are the Air Force, Army, Navy, and Marine sites that are currently participating in our study. The point of contact (POC) is the person located at the dental clinic who will oversee the project at that site.

	Base	POC	Start Date
Air Force	Lackland AFB, TX (3 clinics)	Lt Col (Dr.) Alan Peterson	09/02/2003
	Randolph AFB, TX	Col Carlos Esquivel	09/08/2003
	Wright Patterson AFB, OH	Lt Col (Dr.) Jeff Cigrang	09/02/2003
	Dyess AFB, TX	Lt Col Randall Griffin	11/17/2003
	Sheppard AFB, TX	Capt (Dr.) Bruce Abe	11/18/2003
	Brooks City Base, TX	Maj Jacob Palma	01/07/2004
	Laughlin AFB, TX	Capt (Dr.) Mark Halverson	01/13/2004
	Robins AFB, GA	Maj Elizabeth Tandy	06/06/2004
	Mt Home AFB, ID	Capt. William Quinn	08/03/2004
	Little Rock AFB, AR	Lt Col Robert Abbott	08/24/2004
	Langley AFB, VA	Col Robert Sabatini	09/01/2004
	Nellis AFB, NV	Lt Col Jeff Thompson	09/28/2004
	Eglin AFB, FL	Col Mike Garrett	11/09/2004
Army	Ft. Sam Houston, TX	COL Ronald Lambert	09/18/2003
	Ft. Sill, OK	LTC Charles Sabadell	07/15/2004
	Ft. Polk, LA	COL Thomas MacKenzie	08/16/2004
	Ft. Leavenworth, KS	LTC Robert Windom	08/03/2004
	Ft. Drum, NY	COL Robert Rock	09/04/2004
	Ft. Knox, KY	COL Stephen Rouse	04/05/2005
Navy	North Island Dental Clinic	CAPT Richard A. Joralmon	06/17/2004
USMC	Camp Pendleton, clinic 13	CAPT Wayne Osborne	06/18/2005

Air Force

All of the Air Force sites listed above honored the Wilford Hall Medical Center (WHMC) IRB approval of our protocol, with the exception of Wright-Patterson AFB, OH, Eglin AFB, FL, and Brooks City Base, TX, which have their own IRBs. Our protocol had been previously approved by the Wright-Patterson Medical Center IRB in 2003 and by the Brooks City IRB in Jan 04. Our protocol was expeditiously cleared through both the Eglin IRB later in 2004 to allow us to begin recruiting participants there in November 2004.

Army

Four of the participating Army sites are in the Great Plains Medical Region and thus fall under the authority of the BAMC IRB. They include: Ft Sam Houston, TX; Ft Sill, OK; Ft Polk, LA; and Ft Leavenworth, KS. The BAMC IRB approved our protocol for those sites in expeditious fashion, allowing for recruitment to continue (at Ft Sam Houston) and to begin at Ft Sill, Ft Polk, and Ft Leavenworth in the Jul-Aug 2004 timeframe. The BAMC IRB allowed us to use the short, 4-page enrollment packet that had been approved for the Air Force by WHMC. As a consequence, enrollment at sites in the Great Plains Medical Region has been very good, on a par with AF sites where the shorter enrollment packet is being used.

The remaining Army sites, Ft Drum, NY, and Ft Knox, KY, are in the North Atlantic Medical Region and thus fall under the authority of the Walter Reed Army Medical Center IRB. For these two army sites, we were required to use a lengthier 10-page enrollment packet. The longer enrollment packet has adversely impacted enrollment at Ft Drum, NY, according to POCs at that site, COL Robert Rock and PI/A Jane Bowers. As of yet we do not know the impact of the longer enrollment form at Ft

Knox, KY, as we just began recruitment there in April 05.

North Atlantic Medical Region Army Sites

The process of gaining IRB approval from the Walter Reed Army Medical Center IRB (WRAMC) for enrollment at Ft Drum was quite protracted, lasting at least 12-months. Once the approval was obtained, we were required to use a much longer enrollment packet, i.e., 10 pages long vs. the 4-page enrollment packet approved for AFBs (under the WHMC, Wright-Patterson, and Eglin IRBs) and Army sites in the Great Plains Region (BAMC IRB). As a consequence, enrollment at Ft Drum has been adversely impacted by the longer enrollment forms. The impact of the consent form on enrollment is discussed further in the Reportable Outcomes Section.

Navy and Marines

The process of gaining IRB approval from the Navy Hospital IRB for enrollment at identified Navy and Marine bases was quite protracted as well, lasting 9-months. Again we were required to use a lengthy enrollment packet, i.e., 8 pages long. Recruitment at these sites has also been negatively impacted by the longer enrollment forms. See Reportable Outcomes Section for further discussion.

Processing Amendments to the Original Study Protocol

It has been necessary in the third year of the study to submit several protocol amendments to the governing IRBs. The principal amendments concerned the posting of flyers to advertise the study at each site, changing the second follow-up assessment from 12 months post enrollment to 6 months, and offering cessation materials to Control Group subjects at the time of the 6-month follow-up assessment. We were able to get expeditious approval of amendments from the WHMC, Wright-Patterson, Eglin, and BAMC IRBs for these amendments. However, by contrast, approval by the WRAMC IRB was prolonged and frustrating to investigators because of a lack of responsiveness by WRAMC IRB staff and the seemingly continuous changing of POCs at Walter Reed for processing our amendment requests.

Utilization of Telephone Counseling Guidelines based on Principles of Motivational Interviewing

A crucial part of the intervention in this study is the phone call support given by project phone counselors. We have continued to implement, refine, and monitor the quality of telephone counseling calls that incorporate Motivational Interviewing (MI) techniques to reinforce participants' own motivation for quitting smokeless tobacco. We continue to conduct regular supervision sessions with phone counselors to ensure quality and consistency of counseling calls across counselors and across time.

Utilization of Data Entry/Management System

In this study, data are collected at various points in time at both research sites – Oregon Research Institute (ORI) in Eugene, OR, and Wilford Hall Medical Center (WHMC) in San Antonio, TX. We collect baseline tobacco use data along with consent information from participants at the various dental clinics at the time of participant enrollment. Those data are forwarded by the clinics to ORI for data entry. We collect various data points from participants in the Treatment Group at the time of telephone counseling conducted out of the WHMC research site. We conduct follow-up survey assessments by mail with all participants, in both Treatment and Control Groups, at 3- and 6-months post enrollment and those assessments are both sent and processed at ORI by project staff. If the

participant does not respond to requests to complete the mailed survey, we call them to conduct a telephone survey, using the same questions. These calls are primarily made by WHMC project staff.

In order to centralize and effectively manage the myriad data collected at both sites, we have continued in Year-03 to utilize, and in some cases refine, the Electronic Data Management System developed in Year-02. The system is accessible by research staff at WHMC through a virtual private network (VPN) that completely protects participant confidentiality and allows WHMC research staff in Texas to accomplish data entry and updates as needed. In addition to being a repository for collected data, the system also serves a scheduling function. It schedules the dates for the three counseling calls to Treatment participants, as well as dates for follow-up assessments. The evolving database will provide the basis for all data analysis procedures to be conducted at the conclusion of the data collection phase.

The database development, expansion, and shared input by staff at WHMC and ORI are key activities in the project. The data entry is all done at ORI where the enrollment data and all follow-up data are stored in secure files by participant number. However after randomization of the participant is completed, any participant assigned to the Treatment condition will be contacted by phone. All phone contacts are done by phone counselors at WHMC, and the information they collect is input into the database for that participant. The Virtual Private Network connection, which was developed and implemented in Year-02, allows the phone counselor to enter key data for the participant into the database. The counselor can also access the database prior to the call to determine the degree of the participant's readiness to quit, amount of smokeless tobacco (ST) used, and other relevant information to use in their motivational interview phone calls. This same system is used in the scheduling and tracking of the follow-up assessments at 3- and 6-months.

KEY RESEARCH ACCOMPLISHMENTS IN YEAR 03

- Coordinated expanded recruitment to 14 additional sites: six Air Force Bases, five Army installations, one Navy clinic, and one Marine clinic.
- Initiated formal enrollment of participants at 14 additional military sites
- Processed protocol amendments through all governing IRBs, including WHMC, Wright-Patterson Air Force Medical Center, Eglin Air Force Medical Center, Brooke Army Medical Center, Walter Reed Army Medical Center, and the Naval Hospital in San Diego for the Camp Pendleton Marine Base Clinic 13, and the North Island Naval Base Clinic.
- We are currently requesting approval from the Naval Medical Center in San Diego for adding the 32nd Street Clinic in San Diego.
- In Year 03 we have enrolled 539 additional participants across all participating sites; we collected 271 three-month follow-up assessments and 231 six-month assessments. There were 661 Counseling Calls made in Year 03.
- Continued to utilize and refine an electronic database accessible to project staff at both the ORI and WHMC research sites for data entry and update.
- Developed and implemented an email prompting system to aid in the prompt completion and return of 3- and 6-month mailed assessments by participants in both conditions.

REPORTABLE OUTCOMES

We are in the process of collecting 3-month follow-up outcome measures. No follow-up reportable outcome evaluations have been conducted to date.

CONCLUSIONS

We are still in the enrollment phase of our study and we have no conclusions to report at this time. We have experienced significant delays in our project due to difficulties in the IRB review process and the project is 6 to 9 months behind schedule at this time. There are several points to make on the IRB process. First, the lack of coordination and cooperation between IRB's of the different branches of the service has resulted in both delays and frustration. For example, the review by the WRAMC IRB took 6 months to complete and required significant changes in both the Consent and HIPPA forms to meet their requirements. It should be noted that the protocol had already been approved by the IRBs at Brooke Army Medical Center ant Ft Detrick. Even after the WRAMC review was completed, the final approval was withheld for some time because our materials and WRAMC approval had to first be forwarded to the Medical Research and Materiel Command at Fort Detrick for another review. The review of the approval done at WRAMC was delayed because even an expedited review of the approved protocol required a staff review and memo to the supervisor at Fort Detrick. This resulted in an additional delay of about 8 weeks. Overall, it took about 10 months to obtain WRAMC IRB approval for a study that had already been approved by Wilford Hall Medical Center, Brooke Army Medical Center, the Oregon Research Institute, and Ft Detrick. Additionally, the consent form for enrollment was lengthened by the WRAMC IRB from 1 to 6 pages. As a reminder, this is a minimal-risk study to help military members quit their use of tobacco.

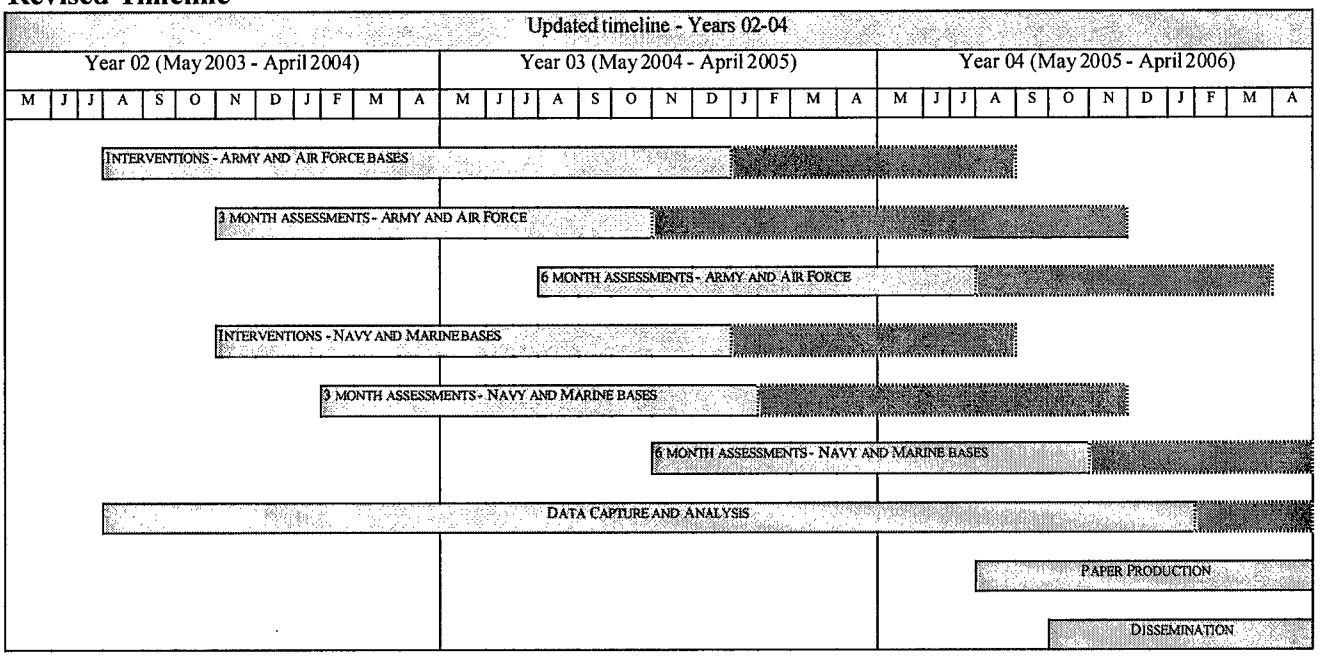
We also experienced a similar delay in the review by the Navy IRB. The Navy IRB had additional unique requirements for their process and the completion and review of our protocol by the Naval Hospital IRB in San Diego took over 6 months. It has been very frustrating to manage a project when we are confronted by numerous obstacles and delays due to numerous IRB reviews. The lack of coordination and cooperation between IRB's of the different branches of the service is a major impediment to conducting research at multiple sites. It is particularly frustrating to us, since this project is of such minimal risk as to be viewed as exempt by some IRB's. We are simply trying to evaluate whether mailed educational materials and phone call support to active duty military personnel can aid in their quitting their use of snuff or chewing tobacco. Unfortunately some IRB's have treated this protocol the same way that one might consider an experimental drug trial. In our opinion there is a lack of flexibility among IRB committees to view a protocol as minimal risk and conduct a population study such as we proposed. Both the Army IRB at WRAMC and the Navy IRB had extensive additional text that needed to be added to the Consent and HIPPA forms and this made the enrollment of participants in the study much more difficult than necessary at sites for which they are the governing authority. The very lengthy consent form required by these IRBs has had a significant negative impact on our ability to adequately recruit participants into the study. As an example of this contract the table below compares the enrollment for bases using different consent procedures. In all cases, the longer consent form has proved to be a significant impediment to participation by military personnel.

During the first 9 months of recruitment:

Short-form			**Long-form**		
Site	**# of Enrollees**	**# of Potential ST users on Site**	**Site**	**# of Enrollees**	**# of Potential ST users on Site**
Ft Sam Houston, TX	**14**	**1,906**	Ft Drum, NY	**5**	**1,559**
Ft Leavenworth, KS	**54**	**754**	Camp Pendleton, CA	**9**	**4,153**
Ft Sill, OK	**50**	**1,906**	North Island Clinic, CA	**5**	**754**

We hope that there is some administrative review of the IRB review process and that procedures are put in place that could provide more timely and coordinated review of protocols that involve minimal risk. We expect to continue enrollment of participants until at least August 2005 in order to maximize our enrollment of study participants and complete our follow-up assessments within the funding period for the project.

Revised Timeline



We will be requesting a no-cost extension to our project to complete data analysis and final reports for the project. The timeline below shows our revised schedule and extended enrollment period to August 2005.

APPENDICES
Enrollment Packets

A. Oregon Research Institute, Eugene OR, Wilford Hall Medical Center, TX, Wright-Patterson AFB, OH, Eglin AFB, FL, and Brooks City Base, TX

B. Water Reed Army Medical Center

C. Naval Medical Center San Diego, CA

APPENDICE A
Enrollment Forms

IRB approved enrollment packet (4-pages) used by:

- Oregon Research Institute;
- Wilford Hall Medical Center;
- Wright-Patterson AFB, OH;
- Eglin AFB, FL; and
- Brooks City Base, TX

1. Consent Form (1-page)
2. HIPAA (1-page)
3. Survey (2-Pages)

«clinic14»

Statement of Informed Consent: Smokeless Tobacco Use in Military Personnel

This clinic is taking part in a smokeless tobacco research study. **If you chew tobacco or use snuff, we would like you to participate in this study.** We would like to get as close as possible to 100% of smokeless tobacco users to participate. The purpose of this study is to assess the effectiveness of a brief intervention on smokeless tobacco cessation.

Your participation involves the following:

1) Filling out the attached survey. **You do not need to be ready to quit smokeless tobacco to participate.** All information collected in this study will be kept confidential. Only research staff will have access to your information. All data will be stored by Oregon Research Institute, and this information will not be available to your dentist, other health care providers, or to anyone in the military.

2) Willingness to be contacted by phone at home or work and be offered a smokeless tobacco cessation program. If you agree to participate, you will be randomly assigned (like the toss of a coin) to the treatment group or the control group. If you are assigned to the treatment group, we will call you to discuss your tobacco use and offer you a cessation program that would help you quit using smokeless tobacco on your own at home. If you are assigned to the control group, you will not receive any phone calls or the cessation program. By agreeing to participate in the study you are not obligated to make a quit attempt even if you are assigned to the treatment group.

3) You will receive two more surveys by mail similar to the one attached, the first in 3 months and the second in 6 months.

Risks The risks involved in participating in this study may include:

1) Loss of confidentiality. We will be getting personal information from you. Your social security number will be used if needed to locate you for follow-up surveys and to document your phone conversations with counselors if you are assigned to the treatment group. There is always the slight possibility that someone who is not authorized might see the personal information that is requested from you. However, it is extremely unlikely that this will occur, and we will take every precaution to assure that your data remain anonymous.

2) Discomfort in discussing your use of tobacco. You may be unaccustomed to talking with someone about your tobacco use. However, our counselors have been extensively trained in this area and will be helpful, courteous, and respectful of your needs.

3) Withdrawal Symptoms. If you quit using smokeless tobacco, you may experience withdrawal symptoms from nicotine cravings such as hunger, anxiety, restlessness, or sleep disturbance. These symptoms are common for persons quitting their addiction to tobacco products. Our counselors have been extensively trained in this area and will be helpful, courteous, and respectful of your needs.

Benefits The benefits of participating in this study are:

1) You could receive a free smokeless tobacco quitting program that may enable you to quit without attending classes or medical appointments. Quitting tobacco may be the most important lifestyle change you can make to improve your health.

2) The information you give us may help other military personnel in the future.

? **YES, I am interested in participating in this study.** (You do not need to be ready to quit to participate.)

By signing below I give my consent for the information I provide on the attached survey to be used by scientists at Oregon Research Institute (Eugene, Oregon). I understand that completing this survey is voluntary, I may choose to skip any question, and that this information will be kept confidential.

I also give my consent to being contacted in the future, possibly offered a smokeless tobacco cessation program, and being sent follow-up surveys in the mail.

Printed name/ with rank	**Signature**	**Date**	**Social Security Number (Optional)**

Home address: _____ Home phone: (____)_____ ☐ prefer daytime ☐ prefer after 1700

(Street, City, State and Zip Code)

Email address: _____ Work phone: (____)_____ ☐ best time is ___morning __ later ☐ best time is after 1600

Put an * next to the number where you prefer to be contacted

? **No, I am not interested in participating in this study.** **AGE**_____years old **SEX:** ? Male ? Female

«clinic18»

HIPAA AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

What is an authorization?
Federal privacy regulations provide safeguards for privacy, security, and authorized access to your personal health information. The Federal Health Insurance & Portability Act (HIPAA) protects the privacy of your personal health information **that [INSERT Dental Clinic NAME HERE]** and Oregon Research Institute collect in the course of this research study. **The only health information that we will access is what you provide in the attached questionnaire. We WILL NOT obtain any information from your dental or medical records.** Health information that identifies you may not be used or disclosed to others for research purposes unless you give written permission in advance.

1. **Authorization.** As a research participant, you authorize Dr. Herbert Severson and Lt Col. Alan Peterson and their research staff to use and disclose your individual health information provided in the attached questionnaire for the purpose of conducting the research project entitled "Population Health Trial for Smokeless Tobacco Cessation with Military Personnel".

2. **Information to be Used or Disclosed.** Your individual health information that may be used or disclosed to conduct the study includes: tobacco use history and demographic information such as age, gender, race, rank, education level, marital status, height, and weight.

3. **Parties Authorized to Disclose Information.** The researcher and the researcher's staff may obtain your individual health information from the attached questionnaire.

4. **Parties Who May Receive or Use Information.** Your individual health information disclosed in the attached questionnaire and information disclosed by you or discovered about you during the course of the research may be disclosed to (1) the study investigators (Dr. Herbert H. Severson and Lt Col Alan Peterson), (2) the sponsor of this research (the Department of Defense U.S. Army Medical Research and Materiel Command), and (3) the Institutional Review Boards that review this research to make sure that it is ethical (Oregon Research Institute, Wilford Hall Medical Center, and Wright-Patterson Medical Center).

5. **Right to Refuse to Sign this Authorization.** You understand that you do not have to sign this Authorization. However, if you do not sign this authorization, you will not be allowed to participate in this research study. Your decision not to sign this Authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. **Right to Withdraw Authorization.** You understand you can change your mind and withdraw this Authorization at any time by sending a **written** notice to Dr. Herbert Severson, 1715 Franklin Blvd, Eugene, OR 97403 or Lt Col Alan Peterson, 59MDOS/MMCP, Wilford Hall Medical Center, 2200 Bergquist Drive, Suite 1, Lackland Air Force Base, TX 78236 to inform the researcher of your decision. If you withdraw this Authorization, the researcher may only use and disclose individual health information already collected for the study. No additional health information about you will be collected by or disclosed to the researcher for the study.

7. **Potential Re-disclosure.** Only as spelled out in #4 above, or in emergencies and/or as required by state law (in the case of child/elder abuse or intent to harm self or others) will information disclosed to others include information that could be used to identify you. If your information is re-disclosed by them, it may no longer be protected by HIPAA.

8. **Expiration of Authorization.** This authorization does not have an expiration date.

I am the research participant. I have read this information, and I understand I will receive a copy of this Authorization when it has been signed.

_____
Name of Participant (type or print)

_____ _____
Signature of Participant Date

23746

Smokeless Tobacco Study

This clinic is taking part in a smokeless tobacco research project. **If you chew tobacco or use snuff**, we would like you to fill out this survey. Filling it out is voluntary and you may choose to skip any question. If you choose not to complete this survey, it will not affect your health care in any way.

IMPORTANT: USE BLACK OR BLUE INK PEN

Shade Circles Like This → ●

Not Like This → ⊗ ✓

For optimum accuracy, please print carefully and avoid contact with the edges of the box. The following will serve as an example:

1	2	3	4	5	6	7	8	9	0

1. Today's date: ☐☐ / ☐☐ / ☐☐
m m d d y y

2. In a typical week, how many days do you use chew/snuff? O 1 O 2 O 3 O 4 O 5 O 6 O 7

3. How many days does a can/pouch last you? O 1 O 2 O 3 O 4 O 5 O 6 O 7 or more

4. How soon after you wake up do you use chew/snuff? O Less than 30 min. O 30 to 60 min. O More than 60 min.

5. How old were you when you began using chew/snuff? ☐☐ years old

6. Do you swallow tobacco juice on purpose? O Never O Sometimes O Almost always

7. Have you tried to quit using chew/snuff in the last year? O Yes O No

8. These statements show how some chew/snuff users feel about quitting. Mark the number that shows how you feel:

Not ready to quit		Should consider quitting some day		Should quit but not quite ready		Thinking about cutting down or quitting		Have cut down and seriously considering quitting		Ready to quit now
O	O	O	O	O	O	O	O	O	O	O
0	1	2	3	4	5	6	7	8	9	10

9. How many of your five best friends use chew or snuff? O None O 1 O 2 O 3 O 4 O 5

Please complete the questions on the back of this page. Thank you for your help!

23746

10. Do you currently smoke? O Yes O No

11. On a typical day, how many cigarettes do you smoke?

O None O 1 to 5 O 6 to 10 O 11 to 15 O 16 to 20 O 21 to 25 O 26 to 30 O 31 or more

12. Does your spouse/partner smoke? O Yes O No O Does not apply

13. Have you had two or more years in your life when you felt depressed or sad most days, even if you felt okay sometimes?

O Yes O No

14. In the past year, have you had two weeks or more during which you felt sad, blue, or depressed, or when you lost all interest or pleasure in things that you usually cared about or enjoyed?

O Yes O No

15. In the past seven days, how many drinks of alcohol did you have? (one drink equals a 12-ounce glass of beer or 6-ounce glass of wine or one shot of liquor)

O None O 1-3 O 4-6 O 7-9 O 10-12 O 13-15 O 16-18 O 19 or more

16. How tall are you? ☐ feet ☐☐ inches **17. How much do you weigh?** ☐☐☐ pounds

18. Your age: ☐☐ years old **19. Sex:** O Male O Female

20. Do you consider yourself to be Hispanic or Latino? O Yes O No

21. What race do you consider yourself to be? Select one of the following:

O American Indian or Alaska Native O Asian O Black or African African American O Native Hawaiian or other Pacific Islander O White

22. Marital Status: O Single O Married or living with partner

23. Education finished:

O Less than high school degree O High school graduate or equivalent O Some college O College graduate O Post college

You are finished. Thank you for your help!

APPENDICES B
Enrollment Forms

IRB approved enrollment packet (10-pages) – Water Reed Army Medical Center

1. Consent Form (6-pages)
2. HIPAA (2-pages)
3. Survey (2-Pages)

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you. If future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) – VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____, SSN _____

having full capacity to consent and having attained my _____ birthday, do hereby volunteer/give consent as legal representative for _____ to participate in _____

Population Health Trial for Smokeless Tobacco Cessation Among Military Personnel

under the direction of **Jane Bowers, Community Dental Health Hygienist, Fort Drum, New York**

conducted at **USA DENTAL ACTIVITY, FORT DRUM, NEW YORK**

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

Jane Bowers, or her designee, Community Dental Health Hygienist, Fort Drum, New York, phone 315-772-7841JS7,

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

JUDGE ADVOCATE GENERAL (JAG) OFFICE, PHONE 315-772-5261

at **FORT DRUM, NEW YORK**

[Name, Address and Phone Number of Hospital (Include Area Code)]

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I /the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I/the person I represent is otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART 8

PART A (2) – ASSENT VOLUNTEER AFFIDAVIT *(MINOR CHILD)*

I, _____ SSN _____ having full capacity to assent and having attained my _____ birthday, do hereby volunteer for _____ to participate in _____

NOT APPLICABLE

under the direction of _____

Conducted at _____

(Name of Institution

(Continue on Reverse)

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PART A(2) – ASSENT VOLUNTEER AFFIDAVIT (MINOR CHILD) (Cont'd)

The implications of my voluntary participation; the nature, duration, and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights I may contact

at

[Name, Address, and Phone Number of Hospital (Include Area Code)]

I understand that I may at any time during the course of this study revoke my assent and withdraw from the study without further penalty or loss of benefits; however, I may be requested to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

LIMITATIONS TO MEDICAL CARE ARE DESCRIBED IN PART B

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25

DESCRIPTION OF THIS STUDY

You are being asked to be in this research study because you answered that you currently use smokeless tobacco at your annual dental exam. Your participation is entirely voluntary. Refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled.

The purpose of this study is to assess the effectiveness of a brief intervention on smokeless tobacco cessation with military personnel.

Other studies have shown that telephone support calls from a trained counselor, together with self-help cessation materials sent by mail, is very effective in helping smokeless tobacco users to quit. This study is based upon a published study with military personnel that used the same procedures. A study has reported that these procedures have also been effective with civilian smokeless tobacco users.

If you agree to be in this study, you will be asked: (1) to fill out the attached survey. This survey includes questions regarding your tobacco and alcohol use as well as your demographics (information such as your age, race, education level, and marital status). **You do not need to be ready to quit smokeless tobacco to fill out the attached initial survey;** (2) to be contacted by phone at home or work and be offered a smokeless tobacco cessation program. If you agree to participate by signing this form, you will be randomly assigned (similar to the flip of a coin) to one of two groups, the Treatment group or the Control group. Your chances of being assigned to each group are equal.

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I do ☐ do not ☐ (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record.

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS NOT-APPLICABLE	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

PART B - TO BE COMPLETED BY INVESTIGATOR (Cont'd)

If you are assigned to the Treatment group, you will receive up to three phone calls. The first call attempt will be made within 1-month upon Oregon Research Institute (ORI, the non-profit research organization conducting this study) receiving the completed enrollment packet (this consent form, the HIPAA authorization form, and the initial survey). Phone counselors, hired and trained by ORI, who have been extensively trained in the area of smokeless tobacco cessation will be making these calls. In the first call you will be offered a smokeless tobacco cessation program that will be mailed to your home. The program includes a 25-minute video tape and a self-help cessation manual. Two additional supportive phone calls will be made to discuss the cessation program, your current tobacco use and how you might apply the program to your own use. The second phone call will be attempted beginning 3-weeks following the date materials are mailed. The third phone call will be attempted either 2-weeks after the second phone call or 2-days following your quit date, should you choose to set a quit date during the second phone call. Each phone call will last up to 20-minutes and all three phone calls will be completed within 3-months of enrolling in this study. If you are assigned to the Control group, you will not receive any phone calls or the cessation program. **By agreeing to participate in the study and completing the initial survey, you are not obligated to make a quit attempt even if you are assigned to the Treatment group.**

Both Treatment and Control groups will be asked to complete and return two more surveys, by mail, the first in 3-months following enrollment and the second in 6-months. These surveys will be mailed to you and will each take 20-minutes to complete. You will be asked to return the completed survey in the provided stamped, addressed envelope. These surveys include questions regarding your health and tobacco use. If you are assigned to the Treatment group and have received the video and manual, each of these surveys will also ask for your feedback about the materials as well as your reaction to the phone counselor.

Both Treatment and Control group participants in the study who do not return the 3-month survey by mail will be contacted by phone and asked to complete the survey over the phone.

AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

You will be part of this study for a total of 6-months. The three surveys will take approximately 15-minutes each to complete. If you are assigned to the Treatment group and choose to receive the intervention, you will receive three phone calls, lasting up to 20-minutes each, a video (25-minutes long) and a manual for viewing.

APPROXIMATE NUMBER OF PEOPLE TAKING PART IN THIS STUDY

This study is called a multi-service study because participants will be recruited from dental clinics located at all four US military branches. There will be up to 600 people taking part in this study at Fort Drum. A total of 1,600 people will be in the study from all of the dental clinics involved.

POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

The risks involved in participating in this study may include:

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS NOT APPLICABLE	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

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PART B - TO BE COMPLETED BY INVESTIGATOR (Cont'd)

(1) Loss of confidentiality. We will be getting personal information from you. Your social security number will be used if needed to locate you for follow-up surveys and to document your phone conversations with counselors if you are assigned to the Treatment group. There is always the slight possibility that someone who is not authorized might see the personal information that is requested from you. However, it is extremely unlikely that this will occur, and we will take every precaution to assure that your information remains confidential.

(2) Discomfort in discussing your use of tobacco. You may be unaccustomed to talking with someone about your tobacco use. However, our counselors have been extensively trained in this area and will be helpful, courteous, and respectful of your needs.

There are no other expected risks or discomforts from being in this study.

POSSIBLE BENEFITS OF BEING IN THIS STUDY

The possible benefits to you from being in this study are (a) you could receive a free smokeless tobacco quitting program that may enable you to quit without attending classes or medical appointments; and (b) quitting tobacco may be the most important lifestyle change you can make to improve your health. However, no benefit can be guaranteed. The information you give us, whether you are assigned to the Treatment or Control group, will help us compare this program to the options already provided to military personnel to assist them in quitting smokeless tobacco use.

CONFIDENTIALITY (PRIVACY) OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep records of your being in this study. All information collected in this study will be kept confidential. All datafiles will be maintained by Oregon Research Institute in Eugene, Oregon. This information will not be available to your dentist, other health care providers, or to anyone in the military. These records may be looked at by people from the Walter Reed Department of Clinical Investigation, the Walter Reed Human Use Committee, the Army Clinical Investigation Regulatory Office (CIRO), the United States Army Medical Research and Materiel Command (USAMRMC, the sponsor of this study), the Institutional Review Boards (committees that review this research to make sure that it is ethical) at Wilford Hall Medical Center (a study site), Wright-Patterson Medical Center (a study site), and the Oregon Research Institute, and other government agencies as part of their duties. These duties include making sure that research subjects are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study.

Every precaution will be taken to assure that the data files remain confidential. Upon completing this consent form and the initial survey, you will be assigned a personal identification number. The assigned personal identification number will not contain any part of your social security number. The consent and survey will

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SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS NOT APPLICABLE	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

PART B - TO BE COMPLETED BY INVESTIGATOR (Cont'd)

be mailed separately from the dental clinic to the Oregon Research Institute (ORI) in Eugene, Oregon where the data will be entered. The data will be stripped of personal identifiers and will be labeled with only your assigned personal identification number. The master list linking your personal identifying information with your assigned personal identification number will be kept in a separate, password encrypted data file to which only the Principal Investigator at ORI, Dr. Severson, and selected professional staff will have access. This master list will be maintained at ORI. Data files will also be password encrypted. All computer data are protected from unauthorized access by industry standard encryption and firewall techniques. All hard copies of data will be kept in locked files. Reports describing the results of this study will in no way reveal your identity. All personnel who have access to your information are instructed not to talk about the study participants publicly by name, and refer to them either by number or first name only. Such procedures are made part of the training and are overemphasized to ensure that these safeguards are maintained. All employees of ORI are asked to sign a Certificate of Confidentiality before being employed with the organization.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA). A HIPAA authorization form for this study will be provided to you separately, and you will be asked to sign that form.

CONDITIONS UNDER WHICH YOUR TAKING PART IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you become ineligible for medical care at military hospitals.

ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

Any active duty military personnel who indicate they are a current smokeless tobacco user is eligible for this study. You will not receive any payment for being in this study.

COMPENSATION TO YOU IF INJURED AND LIMITS TO YOUR MEDICAL CARE

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost to you. You will not receive any compensation (payment) for injury. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics).

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SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS NOT APPLICABLE	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

PART B - TO BE COMPLETED BY INVESTIGATOR (Cont'd)

WHAT WILL HAPPEN IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this research study, send a **written** notice to Dr. Herbert Severson, 1715 Franklin Blvd, Eugene, OR 97403 to inform the researchers of your decision to withdraw from this study. If you withdraw from this study, you will no longer be contacted. Once you withdraw from the study, the researchers may only use and disclose individual health information already collected for the study. No additional health information about you will be collected by or disclosed to the researchers for the study. By leaving this study at any time, you in no way risk losing your right to medical care.

❑ **YES, I am interested in participating in this study.** (You do not need to be ready to quit to participate.)

Home address: _____ Rank: _____

Home phone: _____ ❑ prefer daytime ❑ prefer after 1700

Work phone: _____ ❑ best time is ___A.M. __ P.M. ❑ best time is after 1600

Put an * next to the number where you prefer to be contacted

Email address: _____

❑ No, I am not interested in participating in this study. **AGE** _____years old **Sex:** ❑ Male ❑ Female

Please feel free to ask any questions that will allow you to clearly understand this study.

A copy of this consent form will be provided to you.

Approved by the WRAMC IUC/IRB on 11/10/04 for WU # 04-8200 (1)
This form expires on 04/06/2005 Initials CC

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (If volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS NOT APPLICABLE	
	SIGNATURE OF WITNESS	DATE

REVERSE OF DA FORM 5303-R, MAY 89

Authorization for Research Use of Protected Health Information «clinic10»

Protocol Title: Population Health Trial for Smokeless Tobacco Cessation Among Military Personnel

Principal Investigator: Jane Bowers **Work Unit #: 04-82001**

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

1. What information will be collected?

   For this research study, we will only be collecting personal health information from participants. This information includes; tobacco use history and demographic information such as age, gender, race, rank, education level, marital status, height, and weight.

2. Who may use my PHI within the Military Healthcare System?

   Your PHI disclosed in the attached questionnaire and information disclosed by you or discovered about you during the course of the research may be disclosed to (1) the study investigators, (2) the sponsor of this research (the Department of Defense U.S. Army Medical Research and Materiel Command), and (3) the Institutional Review Boards that review this research to make sure that it is ethical (Walter Reed Army Medical Center Department of Clinical Investigation and Human Use Committee, Wilford Hall Medical Center, and Wright-Patterson Medical Center).

3. What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive my PHI?

   Your PHI disclosed in the attached questionnaire and information disclosed by you or discovered about you during the course of the research may be disclosed to (1) the study investigator, Dr. Herbert H. Severson of the Oregon Research Institute, (ORI) in Eugene, Oregon, (2) the research project staff, and (3) the ORI Institutional Review Board that reviews this research to make sure that it is ethical.

4. What is the purpose for using or disclosing my Protected Health Information (PHI)?

   The investigators of this research project need to use your PHI in order to analyze the information to assess the effectiveness of a brief intervention on smokeless tobacco cessation.

5. How long will the researchers keep my Protected Health Information?

   Data will be maintained by ORI for five years after the completion of this research study at which time all documents and data files will be destroyed.

6. Can I review my own research information?

   You may look at your personal research information at any time.

7. Can I cancel this Authorization?

   Yes. If you cancel this Authorization and stop taking part in this research study, you will no longer be contacted. You can change your mind and withdraw this Authorization at any time by sending a **written** notice to Dr. Herbert Severson, 1715 Franklin Blvd, Eugene, OR 97403 to inform the researchers of your decision to withdraw from this study. Once you withdraw from the study, the researchers may only use and disclose individual health information already collected for the study. No additional health information about you will be collected by or disclosed to the researchers for the study.

8. What will happen if I decide not to sign this Authorization? **«clinic10»**

You understand that you do not have to sign this Authorization. However, if you do not sign this authorization, you will not be allowed to participate in this research study. Your decision not to sign this Authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

9. Can my Protected Health Information be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Army Clinical Investigation Regulatory Office, the Food and Drug Administration, the DHHS Office for Human Research Protections, and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

10. Who should I contact if I have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the WRAMC Privacy Officer, 6900 Georgia Ave., NW, Washington, DC 20307. Telephone: 202-782-3501.

The signature below acknowledges receipt of this Authorization:

Signature: _____ Date: _____

If you are a parent, court-appointed representative, or acting as power of attorney, indicate your authority to act for the participant: _____

Print Name: _____

A copy of this signed Authorization will be provided to you. 7/21/03

23746

Smokeless Tobacco Study

This clinic is taking part in a smokeless tobacco research project. **If you chew tobacco or use snuff**, we would like you to fill out this survey. Filling it out is voluntary and you may choose to skip any question. If you choose not to complete this survey, it will not affect your health care in any way.

IMPORTANT: USE BLACK OR BLUE INK PEN

Shade Circles Like This → ●

Not Like This → ⊗ ✓

For optimum accuracy, please print carefully and avoid contact with the edges of the box. The following will serve as an example:

1	2	3	4	5	6	7	8	9	0

1. Today's date: ☐☐ / ☐☐ / ☐☐
m m d d y y

2. In a typical week, how many days do you use chew/snuff? O 1 O 2 O 3 O 4 O 5 O 6 O 7

3. How many days does a can/pouch last you? O 1 O 2 O 3 O 4 O 5 O 6 O 7 or more

4. How soon after you wake up do you use chew/snuff? O Less than 30 min. O 30 to 60 min. O More than 60 min.

5. How old were you when you began using chew/snuff? ☐☐ years old

6. Do you swallow tobacco juice on purpose? O Never O Sometimes O Almost always

7. Have you tried to quit using chew/snuff in the last year? O Yes O No

8. These statements show how some chew/snuff users feel about quitting. Mark the number that shows how you feel:

Not ready to quit		Should consider quitting some day		Should quit but not quite ready		Thinking about cutting down or quitting		Have cut down and seriously considering quitting		Ready to quit now
O	O	O	O	O	O	O	O	O	O	O
0	1	2	3	4	5	6	7	8	9	10

9. How many of your five best friends use chew or snuff? O None O 1 O 2 O 3 O 4 O 5

Please complete the questions on the back of this page. Thank you for your help!

23746

10. Do you currently smoke? O Yes O No

11. On a typical day, how many cigarettes do you smoke?

O None O 1 to 5 O 6 to 10 O 11 to 15 O 16 to 20 O 21 to 25 O 26 to 30 O 31 or more

12. Does your spouse/partner smoke? O Yes O No O Does not apply

13. Have you had two or more years in your life when you felt depressed or sad most days, even if you felt okay sometimes?

O Yes O No

14. In the past year, have you had two weeks or more during which you felt sad, blue, or depressed, or when you lost all interest or pleasure in things that you usually cared about or enjoyed?

O Yes O No

15. In the past seven days, how many drinks of alcohol did you have? (one drink equals a 12-ounce glass of beer or 6-ounce glass of wine or one shot of liquor)

O None O 1-3 O 4-6 O 7-9 O 10-12 O 13-15 O 16-18 O 19 or more

16. How tall are you? ☐ feet ☐☐ inches **17. How much do you weigh?** ☐☐☐ pounds

18. Your age: ☐☐ years old **19. Sex:** O Male O Female

20. Do you consider yourself to be Hispanic or Latino? O Yes O No

21. What race do you consider yourself to be? Select one of the following:

O American Indian or Alaska Native O Asian O Black or African African American O Native Hawaiian or other Pacific Islander O White

22. Marital Status: O Single O Married or living with partner

23. Education finished:

O Less than high school degree O High school graduate or equivalent O Some college O College graduate O Post college

You are finished. Thank you for your help!

APPENDICE C

Enrollment Forms

IRB approved enrollment packet (8-pages) – Naval Medical Center San Diego, CA

1. Consent Form (4-pages)
2. California Experimental Subjects Bill of Rights (1-page)
3. Privacy Act Statement (1-page)
4. Survey (2-Pages)

1st DENTAL BATTALION NAVAL DENTAL CENTER
CAMP PENDLETON
CAMP PENDLETON, CA 92055-5221

CONSENT BY A *SUBJECT* FOR VOLUNTARY PARTICIPATION IN A CLINICAL INVESTIGATION (RESEARCH) STUDY

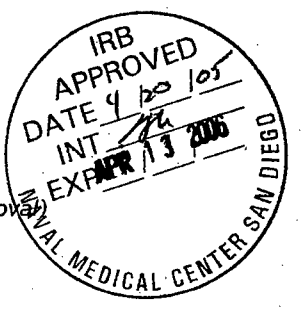
1. You, _____, have been asked to voluntarily participate in a research project entitled, **"Population Health Trial for Smokeless Tobacco Cessation Among Military Personnel"** being conducted at the Naval Medical Center, San Diego by medical researchers from the **1st Dental Battalion Naval Dental Center Camp Pendleton**, in collaboration with (1) Oregon Research Institute, (2) the sponsor of this research (the Department of Defense U.S. Army Medical Research and Materiel Command).

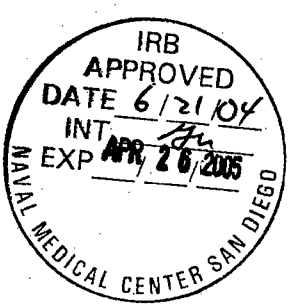
2. WHY IS THE STUDY BEING DONE?
The purpose of this research project is to measure the effectiveness of a brief smokeless tobacco cessation intervention program (designed specifically for use in the Military) compared to the usual preventative health care provided.

3. HOW LONG WILL YOU BE PARTICIPATING IN THE STUDY?
Once you agree to participate in the study you will begin by completing the initial survey. This starts the timer for your involvement. All participants will receive two follow up surveys by mail, the first in three months and the second at six months.

4. WHAT IS INVOLVED IN THE STUDY?
Once you have signed this consent form and have completed the attached baseline survey (2-pages) you will be randomly assigned by chance (like the toss of a coin) to the treatment group or the control group. Neither your doctor, the researcher for this study, nor you will be able to choose the group to which you will be assigned. If you are assigned to the treatment group, we will call you to discuss your tobacco use and offer you a cessation program that would help you quit using smokeless tobacco on your own at home. The program involves receiving a smokeless tobacco cessation guidebook, video and three counseling phone calls. By agreeing to participate in the study and completing the initial survey, you are not obligated to make a quit attempt even if you are assigned to the treatment group. If you are assigned to the control group, you will not receive any phone calls or the cessation program. Again, all participants will be mailed a three month and six month follow up survey to complete and return.

5. WHAT IS THE EXPERIMENTAL PART OF THE STUDY?
The experimental part of this study is to test the intervention program design as well as the effectiveness of the intervention materials designed specifically for use with military personnel in both the short (three month) and long term (six month).





Subject's Initials: _____

IRB Approval Stamp Required
(no alterations should be made to this document w/out prior approval)

6. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 1,600 subjects are expected to participate in this study, of whom up to 200 participants may be from the Naval Medical Center, San Diego.

7. WHAT ARE THE RISKS OF THE STUDY?

The risks involved in participating in this study may include:

1) Loss of confidentiality. We will be getting personal information from you. Your social security number will be used if needed to locate you for follow-up surveys and to document your phone conversations with counselors if you are assigned to the treatment group. There is always the slight possibility that someone who is not authorized might see the personal information that is requested from you. However, it is extremely unlikely that this will occur, and we will take every precaution to assure that your data remain anonymous.

2) Discomfort in discussing your use of tobacco. You may be unaccustomed to talking with someone about your tobacco use. However, our counselors have been extensively trained in this area and will be helpful, courteous, and respectful of your needs.

3) Withdrawal Symptoms. If you quit using smokeless tobacco, you may experience withdrawal symptoms from nicotine cravings such as hunger, anxiety, restlessness, or sleep disturbance. These symptoms are common for persons quitting their addiction to tobacco products. Our counselors have been extensively trained in this area and will be helpful, courteous, and respectful of your needs.

8. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If assigned to the treatment group, the benefits of participating in this study are: (a) you would receive a free smokeless tobacco quitting program that may enable you to quit without attending classes or medical appointments and quitting tobacco may be the most important lifestyle change you can make to improve your health; (b) the information you give us may help other military personnel in the future.

If assigned to the control group, your participation in this research project may not be of direct benefit to you personally. However, the results of this study may help the investigators gain important knowledge about the effectiveness of this smokeless tobacco quitting program as well as aid in determining the availability of such programs for smokeless tobacco users in the future.

9. WHAT OTHER OPTIONS ARE THERE?

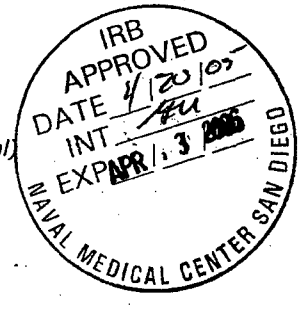
This research study is not designed to treat any medical condition that you may have. Therefore, there are no alternative procedure(s) or course of treatment that would be advantageous to you."

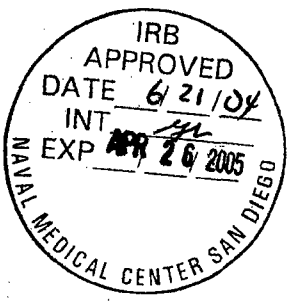
10. WILL I BE PAID TO PARTICIPATE?

You will not be financially compensated for your participation in this study.

Subject's Initials: _____

IRB Approval Stamp Required
(no alterations should be made to this document w/out prior approval)





11. WHAT IF I AM INJURED AS A RESULT OF PARTICIPATION IN THIS STUDY?
If you suffer any injury directly related to your participation in this research study, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your participation in this study will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense, and other state or Federal regulations.

12. WHAT ABOUT CONFIDENTIALITY?
In all publications and presentations resulting from this research study, information about you or your participation in this project will be kept in the strictest confidence and will not be released in any form identifiable to you personally. However, authorized personnel from the Navy Medical Department and from the Food and Drug Administration (FDA), where applicable, may have access to your research file in order to verify that your rights have been adequately protected.

13. WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have any questions regarding this research study, you may contact **CAPT Wayne J. Osborne, at 760-725-8994.**

If you have any questions about your rights as an individual while participating in a research study at the Naval Medical Center, San Diego, you may contact **CAPT George Ulrich, MC, USN, Chairman, Institutional Review Board at (619) 532-8125, or Dr. Warren Lockette, Head, Clinical Investigation Department at (619) 532-8127.**

If you believe that you have been injured as a result of your participation in this research study, you may contact **CDR Steve Bannow, JAGC, USN, Naval Medical Center, San Diego, Legal Department, at (619) 532-6475.**

14. WHAT ARE MY RIGHTS AS A PARTICIPANT?
Your participation in this project is entirely voluntary and your decision not to participate will involve no penalty or loss of benefits to which you are entitled under applicable regulations. If you choose to participate, you are free to ask questions or to withdraw from the study at any time. If you should decide to withdraw from the research project, you will notify **CAPT Wayne J. Osborne, 1st Dental Battalion Naval Dental Center Camp Pendleton, Camp Pendleton, CA 92055-5221, (760) 725-8994 by sending a written notice to inform the researchers of your decision.** You may also contact them by phone to ensure your timely removal from the study. If you withdraw this Authorization, the researcher may only use and disclose individual health information already collected for the study. No additional health information about you will be collected by or disclosed to the researcher for the study. Your withdrawal will involve no prejudice to your future health care or any loss of rights or benefits to which you are otherwise entitled. Any new significant finding developed during the course of this study, which might affect your willingness to continue participation will be communicated to you.

Subject's Initials: _____

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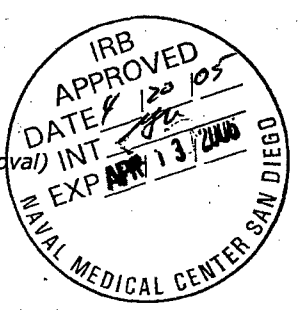

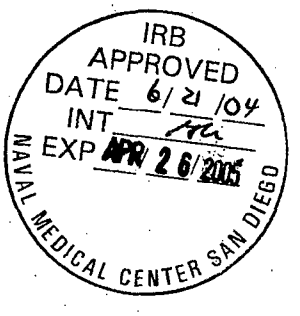

15. CAN I BE TERMINATED FROM THE STUDY?
The investigator may terminate your participation in this study for the following reasons: Participant is deployed for an undisclosed period of time during any phase of the study.

16. SIGNATURE

You are making a decision whether or not to participate in the research project above. Your signature indicates that you have had this information presented to you, have had the opportunity to ask questions about the research and your participation, and agree to participate in the study. Further, your signature indicates that you have been provided with a copy of this consent document and a copy of a document entitled, "California Experimental Subject's Bill of Rights."

❑ **YES, I am interested in participating in this study.** (You do not need to be ready to quit to participate.)

SIGNATURES AND DATE SIGNED: **PRINTED OR TYPED IDENTIFICATION:**

_____ _____
Patient / Subject (Date) Name / Status / Sponsor's SSN

_____ _____
Witness (Date) Name / Grade or Rank

_____ _____
Researcher/Investigator (Date) Name / Grade or Rank

Home address: _____ _____
House/apt number, street City, State, Zip Code

Email address: _____

Home phone: _____ prefer daytime / prefer after 1700 / best time is ___morning __ later

Work phone: _____ best time is after 1600

Put an * next to the number where you prefer to be contacted

❑ **No, I am not interested in participating in this study.** **AGE** _____years old **SEX:** ❑ Male ❑ Female

Subject's Initials: _____

IRB Approval Stamp Required
(no alterations should be made to this document w/out prior approval)

IRB APPROVED DATE 9/20/05 INT _____ EXP APR 13 2006 NAVAL MEDICAL CENTER SAN DIEGO

IRB APPROVED DATE 6/21/04 INT _____ EXP APR 26 2005 NAVAL MEDICAL CENTER SAN DIEGO

PATIENT AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)

(In Keeping with the Health Insurance Portability and Accountability Protection Act)

What is Confidentiality of records all about?

The Naval Medical Center San Diego makes every effort to maintain the confidentiality of protected health information we obtain about you. However, we cannot absolutely guarantee confidentiality because other people may need to see your information in the course of this research study. Most people and organizations will protect the privacy of your information, but may not be required to do so by the law. Also, if the results of this research study are presented at meetings or are published, your name will not be used.

What is HIPAA all about?

The Health Insurance Portability and Accountability Act (HIPAA) requires that we get your permission to use protected health information about you that is either created by or used in connection with this research study. This permission is called an Authorization. The information we use includes your entire research record and supporting information from your medical records, results of laboratory test, X-rays, MRIs, CT scans and observations made by a physician or nurse which are both clinical and research in nature.

What will we do with this information?

Your protected health information will be collected and used during the course of the research study, to monitor your health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests, procedures, and commercial products.

Your research doctor will use this information to report the results of research to sponsors and federal agencies, like the Food and Drug Administration (FDA). The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information and copy it for your records.

Who will we share your information with?

Your information may be shared with any of the following:

- The sponsor of the study, or its agents, such as data repositories
- Other medical centers, institutions, or research investigators outside of the Naval Medical Center San Diego, participating in this research study
- State and Federal agencies which have authority over the research, the Naval Medical Center San Diego or patients. Good examples are: the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institute of Health (NIH), the Office of Human Research Protections (OHRP), and the Department of Social Services (DSS) or other.
- This hospital or clinic.
- Accrediting agencies, such as JCAHO.
- A data safety monitoring board, if applicable
- Clinical staff who may not be involved directly in the research study, but who may become involved in your care, if it is possibly related to treatment

For this research study, the study investigator may share this authorization form and records which identify you to comply with regulatory requirements or for purposes related to this research to:

All documented Principal, Associate, and Sub-investigators, and the Medical Monitor (if one is assigned).

What if you want to revoke or cancel away your Authorization?

If you decide to participate in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke your Authorization, you will also be removed from the study, but standard medical care and any other benefit to which you are entitled will not be affected in any way.

Revoking your Authorization only affects the use and disclosure (sharing) of information after your written request has been received. Federal law requires sending study information to the FDA for studies it regulates, like studies of drugs and devices. In a case like this, your information may need to be reported to them and cannot be removed from the research records once it is collected.

Do you have to sign this form?

You have the right to refuse to sign this Authorization form and not be a part of this study. You can also tell your study doctor you want to withdraw from the study at any time without revoking the Authorization to use your health information. By signing this research Authorization form, you authorize the use and/or disclosure of your protected health information described above.

SIGNATURE AND **DATE** SIGNED:		**PRINTED** OR **TYPED IDENTIFICATION:**
Patient/Subject	(Date)	Name/Status/Sponsor's SSN
Witness	(Date)	Name/Grade or Rank
Researcher/investigator	(Date)	Name/Grade or Rank

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Department of the Navy, the Department of Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at **Naval Hospital Camp Pendleton** and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. I have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

SIGNATURES AND **DATE** SIGNED: **PRINTED** OR **TYPED IDENTIFICATION:**

Patient / Subject (Date) (if Applicable)	Name / Status / Sponsor's SSN
Parent / Guardian (Date) (if Applicable)	Name / Status
Witness (Date)	Name / Grade or Rank

CALIFORNIA EXPERIMENTAL SUBJECTS BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose the experiment;

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be used;

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment;

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable;

5. Be given a disclosure of appropriate alternative procedures, drugs, or devices that might be advantageous to the subject with their relative risks and benefits;

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise;

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved;

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice;

9. Be given a copy of a signed and dated written consent form when one is required;

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision; and

11. Be assured that the subject's confidentiality will be preserved and his/her name will not be released without his/her permission.

Any questions regarding this research study should be directed to the principal investigator or associate investigators. Information is available from the **Chairman, Institutional Review Board**, established for the protection of volunteers in research projects at this facility by calling **(619) 532-8125** or writing the Chairman, Institutional Review Board at Naval Medical Center, Clinical Investigation Department (Code KCA), San Diego, CA 92134-5000.

23746

Smokeless Tobacco Study

This clinic is taking part in a smokeless tobacco research project. **If you chew tobacco or use snuff**, we would like you to fill out this survey. Filling it out is voluntary and you may choose to skip any question. If you choose not to complete this survey, it will not affect your health care in any way.

IMPORTANT: USE BLACK OR BLUE INK PEN

Shade Circles Like This → ●

Not Like This → ⊗ ✓

For optimum accuracy, please print carefully and avoid contact with the edges of the box. The following will serve as an example:

1	2	3	4	5	6	7	8	9	0

1. **Today's date:** ☐☐ / ☐☐ / ☐☐ (m m / d d / y y)

2. **In a typical week, how many days do you use chew/snuff?** O 1 O 2 O 3 O 4 O 5 O 6 O 7

3. **How many days does a can/pouch last you?** O 1 O 2 O 3 O 4 O 5 O 6 O 7 or more

4. **How soon after you wake up do you use chew/snuff?** O Less than 30 min. O 30 to 60 min. O More than 60 min.

5. **How old were you when you began using chew/snuff?** ☐☐ years old

6. **Do you swallow tobacco juice on purpose?** O Never O Sometimes O Almost always

7. **Have you tried to quit using chew/snuff in the last year?** O Yes O No

8. **These statements show how some chew/snuff users feel about quitting. Mark the number that shows how you feel:**

Not ready to quit		Should consider quitting some day		Should quit but not quite ready		Thinking about cutting down or quitting		Have cut down and seriously considering quitting		Ready to quit now
O	O	O	O	O	O	O	O	O	O	O
0	1	2	3	4	5	6	7	8	9	10

9. **How many of your five best friends use chew or snuff?** O None O 1 O 2 O 3 O 4 O 5

Please complete the questions on the back of this page. Thank you for your help!

23746

10. Do you currently smoke? O Yes O No

11. On a typical day, how many cigarettes do you smoke?

O None O 1 to 5 O 6 to 10 O 11 to 15 O 16 to 20 O 21 to 25 O 26 to 30 O 31 or more

12. Does your spouse/partner smoke? O Yes O No O Does not apply

13. Have you had two or more years in your life when you felt depressed or sad most days, even if you felt okay sometimes?

O Yes O No

14. In the past year, have you had two weeks or more during which you felt sad, blue, or depressed, or when you lost all interest or pleasure in things that you usually cared about or enjoyed?

O Yes O No

15. In the past seven days, how many drinks of alcohol did you have? (one drink equals a 12-ounce glass of beer or 6-ounce glass of wine or one shot of liquor)

O None O 1-3 O 4-6 O 7-9 O 10-12 O 13-15 O 16-18 O 19 or more

16. How tall are you? ☐ feet ☐☐ inches **17. How much do you weigh?** ☐☐☐ pounds

18. Your age: ☐☐ years old **19. Sex:** O Male O Female

20. Do you consider yourself to be Hispanic or Latino? O Yes O No

21. What race do you consider yourself to be? Select one of the following:

O American Indian or Alaska Native O Asian O Black or African African American O Native Hawaiian or other Pacific Islander O White

22. Marital Status: O Single O Married or living with partner

23. Education finished:

O Less than high school degree O High school graduate or equivalent O Some college O College graduate O Post college

You are finished. Thank you for your help!